IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. TODD & PATTY MEECH DAIRY FARM, an unincorporated entity, TODD MEECH, and PATTY MEECH, individuals, Defendants.	Case No. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This action is brought on behalf of the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Todd & Patty Meech Dairy Farm, an unincorporated entity, and Todd Meech and Patty Meech, individuals (collectively, "Defendants") from violating:

a. 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) and 342(a)(4);

b. 21 U.S.C. § 331(k), by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), while such drugs are held for sale after shipment in interstate commerce; and

c. 21 U.S.C. § 331(u), by failing to comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332, and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Todd & Patty Meech Dairy Farm ("Meech Dairy Farm" or "Defendants' Farm") is an unincorporated family-owned dairy farm located at 24615 County Road 12, Sebeka, Minnesota, which has approximately 500 cattle, including approximately 400 dairy cows. Meech Dairy Farm sells milk and cows for slaughter for use as food. Meech Dairy Farm is within the jurisdiction of this Court.

5. Defendant Todd Meech is co-owner, with his wife, Patty Meech, of Meech Dairy Farm. He co-manages all aspects of farm operations, including maintaining drug treatment records, administering drugs to animals, and determining which animals to cull for slaughter. He performs his duties at 24615 County Road 12, Sebeka, Minnesota, within the jurisdiction of this Court.

6. Defendant Patty Meech is co-owner of Meech Dairy Farm. She co-manages all aspects of farm operations, including maintaining drug treatment records, administering drugs to animals, and determining which animals to cull for slaughter. She performs her duties at 24615 County Road 12, Sebeka, Minnesota, within the jurisdiction of this Court.

7. Defendants have been and are engaged in the sale of cattle for use as food. The cattle sold by Defendants for slaughter for consumption, and the edible tissues of these animals, are food within the meaning of 21 U.S.C. § 321(f).

8. Defendants cause food to be introduced or delivered for introduction into interstate commerce. For example, Defendants sell cattle for slaughter through local livestock exchanges, Long Prairie Livestock Exchange Market and Perham Stockyards in Minnesota, at which the cattle are purchased and subsequently delivered for slaughter to facilities located outside the state of Minnesota.

9. Defendants medicate their cows with drugs that have been shipped in interstate commerce, including but not limited to Albon (sulfadimethoxine) manufactured in Nebraska and Tylan® 200 (tylosin) manufactured in Northern Ireland. The drugs' distribution across state lines to Defendants in Minnesota constitutes shipment in interstate commerce.

STATUTORY AND REGULATORY PROVISIONS

10. The drugs that Defendants use to treat their cows, including, but not limited to, Albon (sulfadimethoxine) and Tylan® 200 (tylosin), are new animal drugs within the meaning of 21 U.S.C. § 321(v).

11. FDA approves new animal drugs that are shown to be safe and effective for use under specified conditions. 21 U.S.C. § 360b(d)(1).

12. A new animal drug's conditions for use are approved and set forth in the drug's labeling and are published by regulation. *See* 21 U.S.C. § 360b(i); 21 C.F.R. Parts 520-29, 556. The conditions for use include the purposes for which the drug may be used (indications), the maximum amount of the drug or its residues that may be contained in the tissues of animals delivered for slaughter for use as food (tolerances), and the pre-slaughter withdrawal period

required to ensure that treated animals used for food do not have illegal concentrations of the drug remaining in their tissues (withdrawal time). The conditions for use also include the types of animals to which the drug may be administered (species limitations), the amount of drug that may be administered to a specific animal (dosages), and the route of administration. *Id.*

13. A new animal drug is unsafe as a matter of law if the actual use of the drug does not conform to the conditions of the drug's approval. 21 U.S.C. § 360b(a)(1), (a)(4). A licensed veterinarian, in the context of a valid veterinarian-client-patient relationship, may prescribe a new animal drug for a use that differs from that specified in the drug's approved labeling (an "extralabel use"), provided that such use does not result in illegal drug residues in the edible tissues of animals. *Id.*; *see also* 21 C.F.R. §§ 530.10-530.11.

14. Levels of new animal drugs in the edible tissues of animals in amounts above the tolerances established in FDA's regulations, 21 C.F.R. Part 556, pose a significant public health risk. For example, consumers of edible animal tissues who are susceptible to antibiotics may experience severe allergic reactions as a result of ingesting food containing antibiotic levels above established tolerances. Furthermore, antibiotic levels in animal-derived food products (meat, milk, eggs, etc.) contributes to the emergence of antibiotic-resistant strains of bacteria in humans who eat or handle animal-derived food products.

15. A new animal drug detected in an animal's tissue at a level above the tolerance set by FDA or in a species for which it is not approved is unsafe within the meaning of 21 U.S.C. §§ 360b(a)(1), (a)(4).

16. A new animal drug that is unsafe within the meaning of 21 U.S.C. § 360b is deemed to be adulterated. 21 U.S.C. § 351(a)(5).

17. Food containing an unsafe new animal drug is deemed to be adulterated. 21 U.S.C. § 342(a)(2)(C)(ii).

18. The tolerance for sulfadimethoxine in uncooked edible tissue in cattle is 0.1 part per million ("ppm"). 21 C.F.R. § 556.640.

19. The tolerance for neomycin in uncooked edible tissue in cattle is 7.2 ppm in kidney and fat, 3.6 ppm in liver, and 1.2 ppm in muscle. 21 C.F.R. § 556.430.

20. FDA has approved tylosin for use in beef cattle and non-lactating dairy cows via intramuscular injection. 21 C.F.R. § 522.2640. FDA has not approved Tylan® 200 (tylosin) for intravenous use in lactating dairy cows.

REGULATORY HISTORY

March 2017 Inspection

21. FDA most recently inspected Defendants' Farm from December 14, 2016, through March 20, 2017 ("March 2017 Inspection"), as a follow-up to laboratory testing by the United States Department of Agriculture ("USDA") that detected above-tolerance sulfadimethoxine residue in the liver of one of Defendants' cows that Defendants sold for slaughter on June 28, 2016. During the March 2017 Inspection:

a. FDA observed that Defendants do not maintain adequate treatment records for their cattle. Defendants temporarily identify treated cattle with a chalk stick and document the name of the drug and the date it was administered on an erasable white board. Defendants do not retain this information;

b. FDA confirmed that Defendants do not record information regarding administered dosage, estimated animal weight, administration route, the identity of the person administering the drug, withdrawal time for meat and milk, or the date on which the milk or meat can be used;

c. Defendant Todd Meech told the FDA Investigators that Defendants routinely administer Tylan®200 (tylosin) intravenously to lactating dairy cows contrary to the drug's approved use and outside the context of a valid veterinarian-client-patient relationship; and

d. Defendant Todd Meech told the FDA Investigators that Defendants remove ear identification tags of cattle prior to delivery to auction barns and keep no culling or transport records to document cattle delivery.

22. At the close of the inspection, FDA issued a List of Inspectional Observations, Form FDA 483 ("Form 483") to Defendant Todd Meech documenting the following violations:

a. Treatment records were not complete in that the system for identifying treated animals does not record who treated the animal, the dosage administered, the animal's estimated weight, route of administration, withdrawal time for meat and milk or the date which the meat and milk may be used;

b. Failure to identify and maintain records regarding the identity of the animal(s) transported and delivered for sale at an auction yard; and

c. Use of an animal drug, specifically Tylan® 200 (tylosin) in a manner contrary to label directions without benefit of a valid veterinary client-patient relationship.

2014 Inspection

23. FDA previously inspected Defendants' Farm from May 28 through May 29, 2014.

24. The inspection was a follow-up to USDA laboratory testing that detected above-tolerance sulfadimethoxine residue in the liver tissue of a cow Defendants had offered for slaughter for consumption.

25. During the 2014 inspection, FDA documented the same or similar violations as those FDA documented during the March 2017 inspection, including:

a. Defendants caused an unsafe residue of a drug, sulfadimethoxine, to be in the edible tissues of a cow that Defendants offered for slaughter for consumption through use of the drug contrary to its approved labeling;

b. Defendants failed to maintain adequate treatment records for cows that Defendants offered for sale for use as food; and

c. Defendants failed to maintain records regarding the identity of the animal(s) Defendants transported and delivered, which were offered for slaughter for use as food.

26. At the close of this inspection, the FDA Investigator issued a Form FDA 483 to Defendant Todd Meech, documenting violative conditions observed at Defendants' Farm, including those discussed in Paragraph 25.

2006 Inspection

27. FDA previously inspected Defendants' Farm between April 25 and April 27, 2006.

28. The inspection was a follow-up to USDA laboratory testing that detected above-tolerance neomycin residue in the kidney tissues of two cows that Defendants had offered for slaughter for consumption.

29. During the 2006 inspection, the FDA Investigators documented the same or similar violations as those FDA later documented in 2014 or 2017, including:

a. Defendants offered for consumption two cows that contained an unsafe residue of a drug, neomycin, in their edible tissues. The cause of the unsafe residue could not be determined due to Defendants' poor drug treatment and transport recordkeeping;

b. Defendants failed to maintain adequate treatment records for cows that Defendants offered for sale for use as food;

c. Defendants used new animal drugs in a manner contrary to label directions without the benefit of a lawful veterinarian order issued pursuant to a valid veterinarian-client-patient relationship. Specifically, Defendants, without authorization from a licensed veterinarian, administered Penicillin G Procaine in excess of the recommended dosage and administered tylosin, oxytetracycline, and lincomycin hydrochloride to lactating dairy cows. *See* 21 C.F.R. § 522; and

d. Defendants failed to maintain records regarding the identity of the animal(s) Defendants transported and delivered, which were offered for slaughter for use as food.

30. At the close of the inspection, FDA issued a FDA Form 483 to Defendant Todd Meech documenting violative conditions observed at Defendants' Farm, including, but not limited to those discussed in paragraph 29.

Laboratory Testing

31. USDA collected tissue samples from dairy cows that Defendants sold for slaughter for use as food and analyzed those samples for drug residues.

32. USDA's testing on multiple occasions since 2006 revealed above-tolerance new animal drug residues, including sulfadimethoxine and neomycin, in Defendants' dairy cows. Specifically, the drug residues found in cows sold by Defendants for slaughter for use as food include but are not limited to the following:

	Sample Date	USDA Analytical Form Number	Animal	Drug Residue	Tissue	Residue (ppm)	Tolerance (ppm)
a.	08/09/2017	101754572	Dairy cow	Sulfadimethoxine	Liver	0.241	0.1
b.	6/29/2016	101419366	Dairy cow	Sulfadimethoxine	Liver	0.181	0.1
c.	10/23/2013	100625369	Dairy cow	Sulfadimethoxine	Liver Muscle	0.366 0.377	0.1 0.1
d.	03/04/2008	452323	Dairy cow	Sulfadimethoxine	Liver Muscle	1.77 1.14	0.1 0.1
e.	03/14/2006	456910	Dairy cow	Neomycin	Kidney	14.61	7.2
f.	01/10/2006	457748	Dairy cow	Neomycin	Kidney	13.05	7.2

33. Such residues indicate that Defendants failed to administer these drugs in accordance with the dosage, withdrawal time, and/or other use limitations set forth in the drugs' approved labeling.

DEFENDANTS' CONDUCT AND VIOLATIONS

Defendants Violate 21 U.S.C. § 331(a)

34. Defendants' poor recordkeeping practices and improper administration of drugs have resulted in the sale for use as food the edible tissues of cows that contain illegal drug residues.

35. The presence of a drug residue in food above the legally-prescribed limit indicates that a new animal drug has been used in a manner inconsistent with its approved conditions for use. A new animal drug used in a manner inconsistent with its approved conditions for use is deemed unsafe under 21 U.S.C. § 360b(a)(1). Because Defendants have offered for slaughter food that contains unsafe new animal drugs, the food is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(ii).

36. Defendants' poor recordkeeping and improper drug administration practices also constitute insanitary conditions whereby Defendants' food (the edible tissues of their animals) may have been rendered injurious to health, and thus cause the food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4).

37. Accordingly, Defendants violate 21 U.S.C. § 331(a) by causing the introduction and delivery for introduction of adulterated food into interstate commerce.

Defendants Violate 21 U.S.C. § 331(k)

38. Defendants purchase, receive, and administer new animal drugs, including Albon (sulfadimethoxine) and Tylan® 200 (tylosin), to their animals.

39. Defendants hold these drugs for sale after shipment in interstate commerce within the meaning of 21 U.S.C. § 331(k).

40. Defendants' extralabel use of new animal drugs, such as Albon (sulfadimethoxine), has resulted in residues above established safe tolerances. *See* 21 C.F.R. § 556.640. Such drugs, therefore, are unsafe within the meaning of 21 U.S.C. § 360b(a)(1) and, consequently, adulterated within the meaning of 21 U.S.C. § 351(a)(5). *See* 21 C.F.R. § 530.11(d).

41. Defendants' use of Tylan® 200 (tylosin) intravenously in lactating dairy cows is contrary to the drug's approved use. *See* 21 C.F.R. § 522.2640. Defendants' extralabel use is without a lawful order from a licensed veterinarian in the context of a valid veterinarian-client-patient relationship. This unapproved use renders the new animal drug unsafe pursuant to 21 U.S.C. § 360b(a)(1) and, consequently, adulterated within the meaning of 21 U.S.C. § 351(a)(5).

42. Accordingly, Defendants violate 21 U.S.C. § 331(k) by causing drugs to become adulterated within the meaning of 21 U.S.C. § 351(a)(5) while such drugs are held for sale after shipment in interstate commerce.

Defendants Violate 21 U.S.C. § 331(u)

43. Because Defendants do not use new animal drugs in accordance with the drugs' approved conditions for use and/or by or on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship, they do not comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

44. Accordingly, Defendants violate 21 U.S.C. § 331(u) by failing to comply with the requirements under 21 U.S.C. § 360b(a)(4)(A) regarding the extralabel use of new animal drugs.

History of Violations and Warnings

45. Defendants have a long history of violating the Act. Many of the violations documented during FDA's most recent inspection of Defendants' Farm, described in Paragraph 22, are the same as, or similar to, violations documented by FDA during its 2014 or 2006 inspections. At the close of each of these inspections, FDA provided Defendant Todd Meech with a Form FDA 483 documenting the observed violations.

46. Following the 2014 inspection, FDA issued Defendants Todd and Patty Meech a Warning Letter on July 10, 2014, detailing violations observed during that inspection. The Warning Letter emphasized the serious nature of the violations, stated that the list of violations was not exhaustive, and warned Defendants that failure to correct the violations and failure to establish procedures to prevent future violations could result in regulatory action, including an injunction.

47. Following the 2006 inspection, FDA issued Defendant Todd Meech a Warning Letter on August 9, 2006, detailing violations observed during that inspection. The Warning Letter emphasized the serious nature of the violations, stated that the list of violations was not exhaustive, and warned Defendant Todd Meech that failure to correct the violations and failure

to establish procedures to prevent future violations could result in regulatory action, including an injunction.

48. Between January 2006 and August 2016, USDA issued at least six residue violation letters to Defendants. The letters warned Defendants that violative drug residues in the edible tissues of their food-producing animals cause the food to be adulterated, and that FDA had been notified of the findings.

49. Despite these numerous warnings from two federal agencies, Defendants continue to violate the Act. Based on Defendants' repeated violations and failure to take corrective action, the United States is informed and believes that, unless retrained by order of the Court, Defendants will continue to violate the Act.

PRAYER FOR RELIEF

Wherefore, the United States respectfully requests that this Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order from, directly or indirectly:

A. Violating 21 U.S.C. § 331(a) by introducing, delivering, and causing the introduction and delivery for introduction into interstate commerce, any article of food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(2)(C)(ii) or 342(a)(4);

B. Violating 21 U.S.C. § 331(k) by doing or causing to be done any act that causes an article of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(5), while such drug is held for sale after its shipment in interstate commerce; and

C. Violating 21 U.S.C. § 331(u) by failing to comply with the conditions of new animal drug use within the meaning of 21 U.S.C. § 360b(a)(4)(A).

II. Order Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive actual notice of the Court's order, unless and until Defendants bring their operations into compliance with the law to the satisfaction of FDA, to do the following:

A. Cease introducing, delivering, and causing to be introduced and delivered into interstate commerce any article of food within the meaning of 21 U.S.C. § 321(f), excluding milk, consisting of animals and their edible tissues; and

B. Cease administering to animals any new animal drug, within the meaning of 21 U.S.C. § 321(v), while such drug is held for sale after shipment in interstate commerce, unless and until the animal has been examined by a licensed veterinarian who diagnoses the animal and prescribes the administration and dosage of a particular drug for that animal.

III. Authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the costs of inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed; and

IV. Award the United States its costs herein, including the cost of the investigation to date, and such other relief as the Court may deem just and proper.

Date: February 23, 2018

CHAD READLER
Acting Assistant Attorney General

GUSTAV W. EYLER
Acting Director

MONICA C. GROAT
Trial Attorney
Consumer Protection Branch
Department of Justice
Civil Division
P.O. Box 386
Washington, D.C. 20044
(202) 532-4218
monica.c.groat@usdoj.gov

GREGORY G. BOOKER
United States Attorney

By: s/ Friedrich A. P. Siekert
FRIEDRICH A. P. SIEKERT
Assistant U.S. Attorney
Attorney ID Number 142013
600 United States Courthouse
300 South Fourth Street
Minneapolis, MN 55415
(612) 664-5600
fred.siekert@usdoj.gov

Attorneys for Plaintiff
United States of America

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

JENNIFER C. ARGABRIGHT
Associate General Counsel for Enforcement
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4547
Silver Spring, MD 20993
(240) 402-0353
Jennifer.Argabright@fda.hhs.gov